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10/540,123	06/22/2006	Hermann Gohl	52759-215584	1075

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EXAMINER

STEELE, JENNIFER A

ART UNIT	PAPER NUMBER
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1798

NOTIFICATION DATE	DELIVERY MODE
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07/01/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No. 10/540,123	Applicant(s) GOHL ET AL.	
	Examiner JENNIFER STEELE	Art Unit 1798	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/26/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 1, 3, 4, 6, 7, 20-21, 24-25 rejected under 35 U.S.C. 103(a) as

unpatentable over Nohmi et al (US 4,822,489) in view of Nohmi et al (US

4,399,035). Applicant did not amend the claims and the previous rejection of 2/1/2011 is maintained and presented below.

Claim 1 describes a permselective asymmetric hollow fiber membrane suitable for hemodialysis comprising:

- at least one hydrophobic polymer and
- at least one hydrophilic polymer
- wherein said hollow fiber membrane has a four layer structure comprising
 - a first inner separation layer in the form of a dense rather thin layer
 - a second layer in the form of a sponge structure

- a third layer in the form of a finger structure
- and a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 micron, the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²

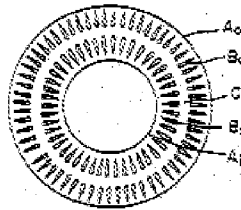
Nohmi '489 is directed to a hollow fiber membrane having a five layer structure with an outer surface, an outer void layer, an intermediate layer, an inner void layer and an inner surface layer. Nohmi '489 teaches the hollow fiber membrane is produced from polysulfone type resin. Nohmi '489 does not teach the polysulfone material is hydrophobic, however Applicant describes polysulfone as hydrophobic. Nohmi '489 teaches the polysulfone fiber can be produced by spinning with a glycol such as ethylene glycol, diethylene glycol, triethylene glycol, polyethylene glycol (col. 9, lines 63-65 and col. 10, lines 44-51) or a polyvinylpyrrolidone (PVP) (col. 10, lines 18-20). Nohmi '489 does not teach a hydrophilic polymer but as Applicant describes the hydrophilic polymer can be a glycol or PVP. Nohmi '489 teaches the same materials as Applicant's specification and therefore the properties are presumed to be inherent or obvious over Nohmi '489.

Nohmi '489 teaches the layers include an outer surface layer A_o, an outer void layer B_o, an intermediate layer C, an inner void layer B_i and an inner surface layer A_i. Where the voids in the void layer have the shape of a cone and are equated with the claimed third layer finger structure. The intermediate layer C has a large number of pores is equated with the second sponge layer. The inner surface layer is equated with

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the first inner separation layer. The outer surface layer is equated with the outer sponge layer as claimed.

FIG. 1

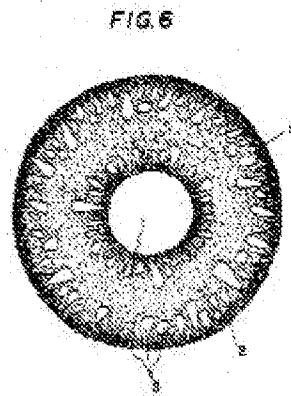


Nohmi '489 differs and does not teach the pore size in the outer surface layer in the claimed range. Nohmi '489 teaches the outer surface has a pore size in the range of 10 to 100 angstroms (col. 3, lines 57-59).

Nohmi '489 differs and does not teach the number of pores on the outer surface.

Nohmi '035 is directed to a hollow filament microfilter (ABST). Nohmi '035 teaches the hollow filament microfilter has a support layer and an internal and external skin layer with an easily controllable and wide average effective pore diameter of 0.05 to 1.0 micron. The hollow filament is characterized by having high selectivity, high permeability, high porosity and excellent mechanical strength and chemical resistance (ABST).

Nohmi '035 is shown below in Fig. 6 where there is an inner layer and an outer layer 1, a support layer 2 which contains macropores and microvoids 3 (col. 13, lines 28-30).



Nohmi '035 teaches the outer skin layer has pore sizes of 0.05 to 1.0 micron and the number and size of the pores in the skin layers are the determining factors for water permeability and permeation selectivity. The greater the number of pores results in a higher permeability and permeation selectivity. Pore size and pore density are results effective variables which when changed or optimized, effect the permeability and selectivity. Nohmi '035 teaches hollow filaments having 1×10^7 to 1×10^{10} pores/cm² can be obtained (col. 12, lines 57-67). 1×10^7 pores/cm² is equivalent to 100,000 pores/mm² which is in the claimed range.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the pore size and pore density in the outer layer motivated to optimize the permeation selectivity.

As to claim 3, Nohmi '489 and Nohmi '035 differ and do not teach the property of diffusive permeability of urea of $15-17 \times 10^{-4}$ cm/sec. As the combination of Nohmi '489 and Nohmi '035 teach the same materials and structure as claimed it is reasonable to presume that the property is inherent or obvious to the combination. And as the combination of Nohmi '489 and Nohmi '035 teach that one of ordinary skill in the art

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could optimize the pore size and density in the skin layer motivated to improve the permeability and selectivity, it would have been obvious to optimize the pore size and density motivated to achieve the desired urea flux.

As to claim 4, Nohmi '489 teaches the thickness of the outer skin layer is almost the same as the inner skin layers and in the range of 0.01 to 10 micron and usually 1 to 4 micron (col. 3, lines 31-36). The inner and outer thickness encompass the claimed range of less than 1 micron for the first separation layer and 1 to 10 micron for the outer layer. Nohmi '489 teaches the second layer or intermediate layer has a thickness of 5 to 70 micron and in the claimed range of 1 to 15 micron. Nohmi '489 teaches the outer void layer with cone shaped voids has a thickness of 10 to 370 micron which is in the claimed range of 20 to 60 micron.

As to claim 6, Nohmi '489 teaches the hollow fiber membrane is produced from a polysulfone polymer.

As to claim 7, Nohmi '489 teaches the hollow fiber membrane can be produced by spinning with a glycol such as ethylene glycol, diethylene glycol, triethylene glycol, polyethylene glycol (col. 9, lines 63-65 and col. 10, lines 44-51) or a polyvinylpyrrolidone (PVP) (col. 10, lines 18-20).

As to claims 20 and 21 which are directed to statements of use, statements of use do not distinguish the claimed invention from prior art. Nohmi '489 is directed to a hollow fiber membrane for ultrafiltration which is in the same field of endeavor as hemofiltration.

As to claims 24 and 25, Nohmi '489 differs and does not teach the pore density on the outer surface.

Nohmi '035 teaches the number of pores on the outer surface can be 100,000 pores per mm² which encompasses the claimed range. It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the pore density motivated to achieve the desired permeability and selectivity.

2. Claim 5 rejected under 35 U.S.C. 103(a) as unpatentable over Nohmi et al (US 4,822,489) in view of Nohmi et al (US 4,399,035) and in further view of Buck et al (US 4,935,141). Applicant did not amend the claims and the previous rejection of 2/1/2011 is maintained and presented below.

As to claim 5, Nohmi '489 and Nohmi '035 teach the amount of glycol, or hydrophilic polymer added is in the range of 0.5 to 30% by weight of the spinning solution but differs and does not teach the composition of the membrane. Nohmi '489 teaches a high amount of glycol, over 30%, produces an unstable spinning solution and produces a membrane that can not be put to practical use (col. 11, lines 1-18).

Buck teaches a permeable asymmetric membrane preferably in the shape of hollow fibers (ABST). Buck teaches a three layer membrane with a dense inner layer of thickness of less than 1 micron, a second sponge layer with a thickness of 5 micron and a third open finger like structure having a thickness of 20 to 60 micron. Buck teaches a hydrophobic polymer between about 85-95% and a hydrophilic polymer between about 5-15% (col. 2, lines 26-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the composition of hydrophobic and hydrophilic polymer motivated to produce a hollow fiber membrane which has water permeability yet has high burst strength.

Response to Arguments

3. Applicant's arguments filed 4/26/2011 have been fully considered but they are not persuasive. Applicant argues that both Naomi '489 and Naomi '035 are directed to symmetric membranes and the membranes have a five layer structure unlike the present claims which recite four layers. Applicant's claims, as written, do not exclude additional layers. Applicant claims the membrane is asymmetric in the preamble. In response to applicant's arguments, the recitation asymmetric has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As Naomi '489 and '035 teach the structural features claimed, the rejection is maintained. Applicant's limitations do not provide any further structural limitations that indicate that the membrane is asymmetrical, the layers are described as a dense rather thin layer, a second sponge layer, a third layer in form of a finger structure and a fourth outer layer in

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the form of a sponge. The dense rather thin layer could be a sponge layer such as the outer layer. As claimed there could be additional layers. The claims do not exclude additional layers or include the structural features which support an asymmetrical membrane structure. Neither Noami '489 nor Noami '035 refer to the membranes as symmetric or asymmetric. Noami '035 refers to a process where if the temperature of the internal and the external coagulating liquids is different, the membrane will be unsymmetrical. Noami '035 presents a finding that one of ordinary skill in the art could make an asymmetrical membrane.

Applicant continues to argue that the instant application has an asymmetric structure comprising a first inner separation layer having the smallest pore size, a second sponge structure, a third layer having a finger structure and an outer layer having a sponge structure with a surface having pores with a defined size and density. Applicant's arguments are not commensurate with the scope of the claims. Applicant has not claimed the pore size of the inner separation layer. Applicant has only claimed the pore size of the outer surface in claim 1.

Applicant argues that the Noami references teach the pores sizes of the selective layers are 0.01 micron and 0.05-1 micron and the membrane of the present application only comprises one selective layer on the inside and unlike the outer layers. Applicant has not claimed the selective layer is the inside layer and has not claimed the pore size of the inside layer. Applicant's arguments are not commensurate with the scope of the claims.

Applicant argues that Examiner presumed the properties to be inherent or obvious over Noami '489, however as the written description of the claims and the Noami references describe clearly different membranes, thus there is no basis for properties to be inherent. As the structural limitations in the claims are taught by the combination of Noami references, Examiner maintains that it is reasonable to presume the properties are inherent or obvious over Noami '489 and '035. Further Applicant has not claimed the pore size of the selective layer, which Applicant has noted is the inner layer. One of ordinary skill in the art would know that the layer with the smaller pore size will limit the flux of the membrane. As Noami '035 teaches the claimed outer layer pore size, it is reasonable to presume that the flux is the same as the claimed invention.

4. Applicant argues that there is no motivation to induce one of ordinary skill in the art to begin with either of the Nohmi references, change the number of layers as well as the sequence of the layers and to move from two identical separation layers on the outside and the inside towards different skin layers. As noted in paragraph 3 above, Applicant's arguments are not commensurate with the scope of the claims. Applicant's claims have not excluded additional layers. Applicant has not claimed a different inner layer from the outer layer. And the order of the layers of Nohmi references combined provide findings that one of ordinary skill in the art could arrange the order of the layers as claimed and select the number of pores on the outer layer as taught by Nohmi '035. Applicant argues that the Nohmi references teach away from reducing the pore number in the outer layers, for instance, Nohmi '035 teaches that "the greater the number of pores, the higher the permeability and the permeation selectivity". According there

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would be no motivation to select pore numbers in the range of 10,000 to 150,000 per mm^2 as required by present claim 1. Nohmi '035 teaches 100,000-100,000,000 per mm^2 . Nohmi '035 teaches a pore density that overlaps the claimed range. As noted above, Nohmi '489 and Nohmi '035 teach the claimed features. If the claimed pore density range is critical to the membrane, the burden is on the Applicant to provide evidence of the criticality of the claimed range. The evidence must be commensurate in scope with the claims.

5. Applicant argues the same argument over the rejection of claim 3 over Nohmi '489 and '035 and the instant invention is not one of optimizing the pore size and density, but the invention of a qualitatively different product. Examiner maintains the rejection over claim 3 for the same reasons as noted over claim 1 in that Applicant is arguing limitations that are not claimed. The only pore size claimed is in the outer layer, however Applicant argues that the inner layer is the separation layer, yet Applicant does not claim the pore size of the separation layer. One of ordinary skill in the art would know that permeability and flux properties are results effective variables of pore size.

6. Applicant argues the rejection over claims 4, 6, 7, 20, 21, 24 and 25 stating that has the instant application has different structural characteristics than the Nohmi references, therefore the obviousness rejection has no basis. Examiner maintains the rejection of claims 4, 6, 7, 20, 21, 24 and 25 over Nohmi '489 and '035 as Nohmi references teach the claimed structural features.

7. Applicant argues the rejection of claim 5 over Nohmi '498, Nohmi '035 and Buck '141. Applicant argues that the office action failed to provide a prima facie case of

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obviousness because the facts stated in the references have been misperceived or misapplied. Applicant state that while Nohmi '489 teaches "the concentration of the polymer in the spinning solution is in the range of 15-35% by weight based on the total weight of the spinning solution" these statements from Nohmi provide no basis to lead one to the instant invention. The fact that the claimed composition is found in the spinning solution would in fact lead one to presume that the composition of the membrane would be approximately the same as the spinning solution depending on the composition of the solution versus the composition of the final formed membrane. However, as the composition of the spinning solution is not equated with the finally formed membrane, Examiner does not rely on Nohmi '489 for teaching this feature. Examiner relies upon Buck for teaching it is known in the art to produce a membrane with the claimed composition of hydrophobic and hydrophilic polymers. The rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on (571) 272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1798

/Angela Ortiz/
Supervisory Patent Examiner, Art
Unit 1798

6/22/2011